

REMARKS

Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 were pending and examined in the Office Action dated May 10, 2006. Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 were rejected in that Office Action. No claims have been added, modified, or deleted by this Response. Applicants respectfully request reconsideration of this application.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 stand rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Alt (5,855,600) in view of Zhu, et al. (6,399,215). Applicants respectfully point out that the Examiner applied the Alt '600 patent in the Office Action dated 11/25/05, and applied the Zhu '215 patent in the Office Action dated 6/29/04. In the present sixth non-final Office Action, the Examiner has resorted to a combination of previously applied references that have failed and continue to fail to anticipate or render obvious Applicants' pending claims.

To establish a *prima facie* case of obviousness, the Examiner must provide one or more prior art references that teach or suggest each and every claim limitation of Applicants' claims – MPEP § 2142. Applicants respectfully submit, however, that the Examiner has not carried that burden. Furthermore, Applicant respectfully submits that it is the burden of the Examiner to apply each of the elements of Graham, namely to identify the level ordinary skill in the art, which has not been done -- see MPEP §§ 2141, 2141.03.

CLAIMS 1, 3-10 AND 14-16

Applicants' independent claim 1 and dependent claims 3-10 and 14-16 recite "a metal alloy substrate having an average grain size in the range of one to ten microns." The Alt '600 patent discloses a medical device, namely a stent, made from a metal alloy, for example, stainless steel. As the Examiner acknowledges, the Alt '600 patent does not

teach that the disclosed stent is made from a material (substrate) that has an average grain size of one to ten microns. The Zhu '215 patent discloses processing commercially pure titanium (col. 4, lines 28-30) to provide a billet of "ultrafine-grained titanium" for use in certain medical implants. No starting materials other than commercially pure titanium are disclosed in the Zhu '215 patent. Neither cited reference teaches or suggests a metal alloy having an average grain size in the range of one to ten microns.

As Applicants understand the rejection, the Examiner is of the opinion that Applicants' claimed metal alloys (e.g., stainless steel, cobalt-chromium, nickel-titanium) could be substituted for commercially pure titanium as a starting material in the Equal Channel Angular Extrusion (ECAE) process disclosed in the Zhu '215 patent. Applicants respectfully disagree with the Examiner that such a "mere substitution" would have been obvious to one having ordinary skill in the art. To support an obviousness rejection there must be some suggestion or motivation to modify a reference or combine reference teachings -- see MPEP § 706.02(j). Without such a teaching or suggestion to modify the reference, the Examiner is using improper hindsight to glean from Applicants' teachings that which is not disclosed in the cited reference. See In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

There is nothing in the Zhu '215 patent that would suggest or motivate one of ordinary skill in the art to substitute a metal alloy for the commercially pure titanium used in the ECAE process -- see MPEP § 2143.01. Moreover, there must be a reasonable expectation of success with such a substitution, and Applicants submit that those of ordinary skill in the art in possession of the Zhu '215 patent alone would not reasonably expect the ECAE process to yield fine-grained metal alloys as claimed by Applicants. Accordingly, the Examiner's substitution of metal alloys for commercially pure titanium in the process disclosed in the Zhu '215 patent is an impermissible "obvious to try" rejection -- see MPEP § 2145.X.B.

Applicants believe that Zhu et al. teach away from using an alloy in the ECAE process, since the stated purpose of the disclosed process is to provide a replacement or an alternative for titanium alloy implants (see col. 2, lines 25-36; col. 7, lines 4-8). Accordingly, the Zhu '215 patent begins with a commercially pure titanium billet having a mean grain size of ten microns, which they refer to as "coarse-grained" (see col. 3, lines 1-3; col. 4, lines 41-45; Table 2), and process the ten micron starting material into a "ultrafine-grained titanium billet" having a mean grain size of about 0.26 microns (see col. 4, lines 25-36), which is outside of the grain size range claimed by Applicants. Moreover, after six Office Actions, the Examiner has yet to cite a reference that teaches a metal alloy having a grain size of one to ten microns, which is the grain size of the starting material used in the Zhu '215 patent process. The Examiner's attention is also directed to references cited in Applicants' Supplemental Information Disclosure Statement filed September 27, 2004, which discuss the difficulties of using alloys in the ECAE process.

Thus, Applicants respectfully submit that the rejection of Applicants' claims 1, 3-10 and 14-16 under § 103(a) is improper and should be withdrawn.

CLAIMS 22-24 and 26-29

Applicants' independent claim 22 and dependent claims 23-24 and 26-29 recite an intravascular stent having cylindrical rings "formed from a fine grained material having an average grain size of one to ten microns." As discussed herein there is no teaching or suggestion to combine the references applied by the Examiner. The Zhu '215 patent does not mention intravascular stents having cylindrical rings as a suitable medical implant for its processed titanium. Moreover, even if the teachings of Alt '600 and Zhu '215 patents were combined, the result would not teach each and every element of Applicants' claimed invention. The Alt '600 patent does not teach a stent having cylindrical rings made from a material having a grain size of one to ten microns, and Zhu '215 patent does not solve the deficiencies of Alt '600.

The Zhu '215 patent begins with a titanium billet having a mean grain size of ten microns, which they refer to as "coarse-grained" (see col. 3, lines 1-3; col. 4, lines 41-45; Table 2), and process the ten micron starting material into a "ultrafine-grained titanium billet" having a mean grain size of about 0.26 microns (see col. 4, lines 25-36), which is outside of the grain size range claimed by Applicants. The substrate used in the Zhu '215 patent to manufacture medical implants is the ultrafine-grained titanium billet of less than one micron (see col. 6, lines 45-50). Nowhere in the Zhu '215 patent is there a teaching of forming a medical implant from a substrate having a grain size between one and ten microns. Indeed, when Zhu et al. obtain an intermediate billet of two to four microns, which they call "coarse grained," they teach continued processing of the titanium until it becomes "ultrafine-grained" (col. 6, lines 28-44). Thus, the Zhu '215 patent teaches using the ultrafine-grained titanium as a substrate for a medical implant, and teaches away from using a substrate having an average grain size of one to ten microns.

Accordingly, Applicants respectfully submit that the rejection of Applicants' claims 22-24 and 26-29 under § 103(a) is improper and should be withdrawn.

CLAIMS 41-45

Applicants' independent claim 41 and dependent claims 42-45 recite a stent comprising "a substrate having an average grain size of one to ten microns." As discussed herein regarding independent claims 1 and 22, there is no teaching or suggestion to combine the references applied by the Examiner. The Zhu '215 patent does not mention stents as suitable medical implants for its processed titanium. Moreover, even if the teachings of Alt '600 and Zhu '215 patents were combined, the result would not teach Applicants' claimed invention. Nowhere in either the Alt '600 or Zhu '215 patents is there a teaching of using a substrate having a grain size between one and ten microns to form a medical implant, such as a stent. Thus, the combination of the cited references does not teach each and every element of Applicants' independent claim 41.

Accordingly, Applicants respectfully submit that the rejection of Applicants' claims 41-45 under § 103(a) is improper and should be withdrawn.

CONCLUSION

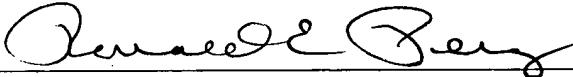
In view of the foregoing, Applicants respectfully submit that all presently pending claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 are in condition for allowance, and that the application should be passed to issue. The Examiner is encouraged to contact the undersigned should there be any questions or resolvable matters regarding this application.

Respectfully submitted,

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